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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,785	07/03/2003	Syncse Jolidon	21288 US	6999

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

KUMAR, SHAIENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,785	Applicant(s) JOLIDON ET AL.	
	Examiner SHAILENDRA - KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-13, 15 and 17 is/are allowed.
- 6) ☒ Claim(s) 1-7, 14, 16, 18, 20 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/6/03, 12/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 are pending in this application.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/6/04 and 12/5/2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include Nature of the invention, breadth of the claims, guidance of the specification, the existence of the working examples, predictability of the prior art, state of the prior art, and the amount of the experimentation necessary. All of the Wands

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factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: Claims 24 and 25 are drawn to the method of treating or preventing Alzheimer's disease or senile dementia by administering the claimed compounds and composition.

Breadth of the claims: The complex nature of the claims greatly exacerbated by breadth of the claims. The claims encompass treating Alzheimer's and senile dementia in an individual.

Guidance of the specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treat the said diseases. The guidance is limited to the preparation of the composition including the weight of the tablet.

Working examples: No working examples have been provided. All the examples are directed to the preparation of the compounds.

State of the art: The state of the art is that there is no treatment available for the claimed diseases. There is no known agent that can treat or prevent the claimed diseases.

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment or the prevention in an individual with the claimed compounds makes practicing the claimed method unpredictable.

The quantitation of experimentation necessary: In the absence of the any experimental data provided, applicants have not provided any guidance to allow the skilled artisan to practice the invention, and one of ordinary skilled in the art will have to do undue

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experimentation. The specification is merely limited to the disclosure of the MAO related studies and no definite relationship has been provided with respect to the Alzheimer's or senile dementia.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-6, 14, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2,645,019.

FR'019, page 44, lines 25-26 anticipate instant claims, when in the instant claims A is CH₂CH₂, R₂₁, R₂₂, R₂₃, R₂₄, and R₃ are hydrogen and R₁ is halogen, n is 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7, 14, 18, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR'019.

FR'019 teach structurally similar compounds as claimed herein, see for example, lines 25-26 on page 44. The difference between the reference and herein claimed compounds is that in herein benzyloxy phenyl is substitute with F as against Cl in the reference and R3 can be methyl in herein as against hydrogen in the reference.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds having fluoro substituent on the benzyloxy phenyl group of the reference because F and Cl are equivalent, or alternatively substitute methyl for hydrogen for R in the reference, because hydrogen

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and methyl are equivalent, Ex parte Bluestone, 135 USPQ 199, with the reasonable expectation of achieving a successful composition, absent evidence to the contrary.

11. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR'019.

Instant claims are directed to a process of preparing compound of formula IV of claim 23 and compound of formula I of claim 1, starting with benzyl compound having a leaving group and reacting with hydroxy containing amido compound, or reacting ester with an amine.

FR'019 on page 7 teaches analogous process wherein benzyl chloride is reacted with a phenol to obtain benzyloxy compound, also see, page 15. Also on page 16, reaction of ester with an amine is taught similar to herein to form an amide. Also see example on page 44, lines 28-35. The difference between the references and herein claimed process is the different starting material and end product.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the process of FR'019 by using starting material similar to herein, with reasonable expectation of achieving a product similar to claimed herein, because the process is analogous.

12. Claims 8-13, 15, 17 are free of prior art and are allowable.

13. Claims 19, 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
9/17/04